

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D2171610	(X3) Date Survey Completed 06/11/2025
Name of Provider or Supplier Weil Foot & Ankle Institute, Llc	Street Address, City, State 1660 Feehanville Dr Suite 450, Mount Prospect, IL	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures, laboratory records, lack of documentation, and interview with testing personnel (TP) #1; the laboratory failed to ensure positive and negative control materials were tested each day of patient testing for five of six patients reviewed in the specialty of microbiology from 2023 through the date of survey, 06/11/2025. Findings include: 1. Review of laboratory policies and procedures revealed the policy titled, "Quality Control Monitoring", which stated, under "E. Procedures", "Quality control/function checks are run weekly for each instrument in use All quality control values must yield the proper positive or negative result." 2. Review of laboratory records found the following pathogens and antibiotic resistance markers (ABRs) tested on the Wound and Nail Polymerase Chain Reaction (PCR) Panels: Pathogens: Sarocladium strictum (Acremonium strictum) Aspergillus flavus Aspergillus fumigatus Aspergillus niger Aspergillus terreus Aspergillus versicolor Candida albicans Nakaseomyces glabrata (Candida glabrata) Pichia kudriavzevii (Candida krusei) Candida parapsilosis Candida tropicalis Epidermophyton floccosum Microspora canis complex Neoscytalidium dimidiatum Scopulariopsis brevicaulis Trichophyton interdigitale / mentagrophytes Trichophyton rubrum Trichophyton verrucosum Acinetobacter baumannii Bacteroides fragilis Coagulase-negative Staphylococcus species Corynebacterium striatum Enterococcus faecalis Enterococcus faecium Escherichia coli Finegoldia magna Klebsiella pneumoniae Mycobacterium chelonae / abscessus Mycobacterium fortuitum Mycoplasma pneumoniae Proteus mirabilis Pseudomonas aeruginosa Serratia marcescens Staphylococcus aureus Staphylococcus epidermis Streptococcus agalactiae Streptococcus dysgalactiae Streptococcus pyogenes ABRs: Class C beta-lactamase resistance (DHA) Macrolide lincosamides streptogramins (ermA)</p>

Macrolide lincosamides streptogramins (ermB) MRSA*/beta-lactamase resistance (mecA) Tetracycline resistance (tetM) Vancomycin resistance (vanA) Vancomycin resistance (vanB) *MRSA = Methicillin Resistance Staphylococcus Aureus 3. Review of laboratory quality control (QC) records for five of six patient testing dates reviewed for Wound and Nail OCR Panels found positive and negative were not utilized on each day of patient testing. Date: Patient: QC Performed: 07/25/2023 14642 Not performed 12/27/2023 15115 Performed 05/13/2024 15150 Not performed 09/09/2024 16146 Not performed 02/10/2025 17157 Not performed 03/24/2025 17741 Not performed 4. Interview with TP #1 on 06/11/2025, at 12:47 pm, confirmed the laboratory failed to ensure positive and negative control materials were tested each day of patient testing for five of six patients reviewed in the specialty of microbiology from 2023 through the date of survey, 06/11/2025.